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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/431,821	11/02/1999	DOUGLAS TRECO	50010/006006	9257

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04/26/2002

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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/431,821

Applicant(s)

TRECO ET AL.

Examiner

James S. Ketter

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 March 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 28 March 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): both obviousness-type double patenting rejections.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: (see attached sheets).
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.Claim(s) objected to: 75 and 76.Claim(s) rejected: 65-74, 77 and 78.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

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Applicants have overcome the obviousness-type double patenting rejections.

Claims 75 and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 65-72, 74, 77 and 78 stand rejected under 35 U.S.C. 102(e) as being anticipated by Sherwin et al., for reasons of record.

In the amendment after final, filed 28 March 2002, Applicants argue that the claims require targeting and expression in the same cells or progeny thereof, and that Sherwin et al. only teach expression of the gene of interest after being moved to a different cell line. Applicants suggest that the reference has been misunderstood because of the different definitions of "primary" and "secondary" cells in Sherwin et al. as contrasted with their definitions in the instant application. However, the uses of the terms have been reviewed, and it is believed that no such misunderstanding exists. The issue revolves around the extent to which Sherwin et al. teaches the expression of a gene product of interest in the cells initially transfected using homologous recombination, i.e., gene targeting. Applicants argue that the fourth and fifth paragraphs of column 3 of Sherwin et al. must be cells other than those wherein targeting occurs, as said cells are described as "host" cells. However, it is clear from the fourth full paragraph of column 3 that the cells which have been initially targeted with the construct of interest are screened for expression of the protein. Thus, Sherwin et al. teaches production of protein from the same cells or progeny thereof, which cells were transfected using homologous recombination

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to increase expression of the gene of interest. Sherwin et al. thus teaches a 2-part invention, with the first part being gene targeting followed by expression to test for success, and the second part being moving the modified DNA from the genome of the first cell (line) to another cell (line), to further improve expression. Further, the first and second paragraphs of the SUMMARY OF THE INVENTION (column 2) make clear that targeting, amplification and expression are performed, and that the step of moving the DNA to the second cell is optional ("*may* then be transferred to a secondary host", column 2, line 37, emphasis added).

Claims 65, 72 and 73 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sherwin et al. in view of Capecchi, for reasons of record.

Applicants' arguments are based upon those made against the rejection under 35 USC § 102(e), addressed supra. Accordingly, said arguments have been addressed supra.

Certain papers related to this application may be submitted to the directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant

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is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

Questions regarding formalities and processing of the case should be directed to Zeta Adams, whose telephone number is (703) 305-3291.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
April 25, 2002



**JAMES KETTER
PRIMARY EXAMINER**